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Leprosy

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Leprosy has been referred to as one of the oldest diseases known to humankind. The earliest written records describing true leprosy come from India and there it was known as *kushta*. It is believed that from India it spread eastward to China and Japan and then westward to the lands bordering the Mediterranean. During the fourteenth century, the leprosy epidemic reached its peak in Europe. During the height of the epidemic there may have been as many as 2,000 hospices in France alone to care for the victims of leprosy (Browne 1985). The influence of the Crusades on the spread of leprosy in Europe and the effect of the "Black Death" (which wiped out a third of the population of that continent in 1349) on the decline of the leprosy epidemic has long been debated. For reasons still unknown, Europe was rid of the disease by the early nineteenth century. The last known indigenously contracted leprosy case in Britain was diagnosed in 1798 (Browne 1985). This decline of leprosy prevalence in Europe even before the advent of effective treatment and a century before the discovery of sulfone drugs has been mainly attributed to the changing socioeconomic environment brought about by the industrial revolution.

Leprosy is an infectious disease caused by *Mycobacterium leprae*. The host response to this infectious agent depends on the cellular immune mechanism. A person with a good cellular immune response who develops leprosy is more likely to have the milder tuberculoid type, whereas those with weak or lacking cellular immunity are likely to develop the lepromatous type (Bloom and Godal 1983).

The clinical spectrum of leprosy varies from a single benign hypopigmented skin patch that may heal spontaneously to widespread damage to nerves, bones, eyes, muscles, and kidneys. Long-standing disease may produce severe mutilation of the face and extremities, making the psychological trauma of leprosy victims at least as important as the physical suffering. The Ridley and Jopling classification system (Ridley 1974) defines the immunological spectrum of leprosy in clinical and histological terms, dividing it into indeterminate (I), tuberculoid (TT), borderline tuberculoid (BT), borderline (BB), borderline lepromatous (BL), and lepromatous (LL) types. The multibacillary form of the disease (BB, BL, and LL) is highly infectious and strongly positive on bacterial examination, whereas the paucibacillary form (I, TT, and BT) is generally less infectious and is bacteriologically negative.

Onset of leprosy is usually gradual, and the first signs may not be apparent for quite some time after infection. The insidious onset and uncertain time of exposure make it difficult to calculate the exact incubation period. The average incubation period of leprosy is estimated to be two to four years, though it may vary from nine months to twelve years (WHO 1985b).

Before the days of modern chemotherapy for leprosy, the duration of illness was lifelong for some cases. Even with the discovery of dapsone, lepromatous cases were treated for life. With the recent discovery of newer drugs, the duration of illness has been drastically reduced. The World Health Organization now recommends that duration of treatment for a paucibacillary case be six months and for a multibacillary case, two years or until the skin smear becomes negative (WHO 1982), which may be on average three and one-half years. Even though the present therapy still takes months and sometimes years to cure a patient, when compared with previous treatments, it has greatly improved the prospects for a quick cure.

Since patients rarely die of leprosy, the case-fatality rate is negligible (Walsh [1988] estimates it is 0.1 percent). A few may die from complications of septic wounds or from severe reactions. This low case-fatality rate has made the disease appear to be less serious, especially when priorities are being set for health care by politicians and health administrators according to mortality rates and public outcry. Leprosy tends to be given a low priority, but the disability and economic loss it causes, along with the social and psychological problems the patient and his or her family suffer, make it more than an insignificant disease.

The disability suffered by leprosy patients is a secondary consequence of nerve damage caused by infection with M. *leprae*. The resulting anesthesia makes leprosy patients vulnerable to accidental injury of anesthetic tissue. In 1970 WHO formulated a disability grading system which categorized disability from such injury into three grades. The system has since been simplified. It is still a three-grade system (grades 0, 1, and 2 rather than grades 1, 2, and 3) with two separate sets of criteria, one for the hands and feet,

and one for the eyes. The new grade 2, however, includes the previous grades 2 and 3.

The current grading system is as follows. For the hands and feet, the criteria for grade 0 are no anesthesia and no visible deformity or damage. A grade 1 condition is indicated by the presence of anesthesia, but no visible deformity or damage, whereas grade 2 is indicated by the presence of visible deformity or damage. Each hand and foot is to be assessed and graded separately. "Damage" in this context includes ulceration, shortening, disorganization, stiffness, and loss of part or all of the hand or foot. For the eyes, criteria for grade 0 are no eye problems due to leprosy and no evidence of visual loss. Grade 1 is indicated by the presence of eye problems due to leprosy but with vision remaining at six-sixty or better or the ability to see well enough to count fingers at 6 meters. Visual impairment is classified as grade 2 when vision is worse than six-sixty or the patient is unable to count fingers at 6 meters. "Eye problems due to leprosy" include corneal anesthesia, lagophthalmos, and iridocyclitis. Each eye is to be assessed and classified separately (WHO, Regional Office of the Western Pacific 1988).

The percentage of untreated patients who are disabled may reach 50 percent if the less serious forms (grade 1) of anesthesia arising from peripheral nerve trunk involvement are considered. If only the more serious forms (currently grade 2) of disability are considered, the percentage is about 32 percent (WHO 1980). Among the newly diagnosed patients, the percentage who are disabled (all grades) ranges from 2.7 percent in India (Mittal 1991) to 16 percent in some areas of Myanmar (formerly Burma) (Myint, Htoon, and Shwe 1992). Although multidrug therapy has reduced the occurrence of disability, the proportion of treated patients who are disabled remains high in some areas because many patients are diagnosed after irreversible nerve damage has occurred. Early diagnosis and treatment are thus important in reducing the proportion of disabled patients. Another reason that disability may remain common is the failure of leprosy control programs to incorporate the use of simple technologies for disability prevention as well as patient education. It must be noted, however, that despite rigorous efforts, even regarding early diagnosis and treatment, some patients will develop disability.

The World Health Organization has estimated that two-thirds of the leprosy cases in the world are still unregistered, so there may be as many as 2 million undetected, partially disabled patients (grade 2) in addition to the registered cases. It is estimated that 250,000 of those with leprosy are blind (vision three-sixty). This figure increases if a visual acuity of less than six-sixty is considered (Courtwright and Johnson 1988).

The clinical entity of leprosy represents a spectrum of immunological reactions to infection by *M. leprae*. Some patients have skin patches only (uncomplicated leprosy), and others have skin lesions complicated by immunological reactions ranging from mild to serious, producing such conditions as neuritis, iritis, and increased inflammatory response in the skin lesions. Very little is known about the incidence of reactions in leprosy patients because of the problems in defining the appropriate denominator, the total number of cases of the disease. Data on reaction incidence are usually from clinic sources, but many undetected cases exist which are not counted in clinic data.

There was initial concern that with the introduction of new bacteriocidal drugs in multidrug therapy, more patients might have reactions due to the release of antigens from the killed bacilli. But the results of studies of reaction incidence are encouraging. In a study by Boerrigter, Ponnighaus, and Fine (1988), the rates of the more serious type I reactions range from 76.9 per 1,000 person-years to 43.6 per 1,000 person-years in paucibacillary cases treated with the WHO multidrug therapy regimen. (Reactions are discussed later in this chapter.) Other secondary complications of leprosy infections include tissue necrosis, plantar ulceration, secondary bacterial cellulitis and osteomyelitis, and progressive absorption of the digits of the hands and feet.

Distribution and Risk Factors

Although leprosy is one of the oldest diseases known to humankind, very little is known about its natural history. The mode of transmission is still not known with certainty. The isolation of bacilli from loosened squamous epithelium of intact skin and from nasal washings of untreated lepromatous cases has led to the hypothesis that the portals of exit are ulcers on the skin and the respiratory tract (WHO 1985b). The two widely accepted modes of transmission are direct skin-to-skin contact and droplet dispersion, but there is still no clear-cut evidence to support their role in the spread of infection.

Age Distribution

The incidence of leprosy is bimodal. The first peak occurs between the ages of ten and twenty years and the second peak between the ages of thirty and fifty (Dominguez and others 1980). Clinical leprosy may occur in infants, but it does so rarely and only in children of those with the disease.

Sex Distribution

In most endemic countries both the prevalence and the incidence of leprosy is higher in males than in females. The higher occurrence in males has been attributed to the greater mobility of males, which provides greater opportunity for exposure and contact with infectious cases. It may also be attributable to failure to detect disease in females because of social attitudes, which result in less thorough examination of females by health workers. In a cohort study conducted in Myanmar from 1964 to 1976 in a population of 61,000 people living in highly endemic areas, the prevalence of leprosy for males was 42.2 per 1,000 and that of females was 32.6 per 1,000. The incidence rate for males and females was 7.0 per 1,000 per year and 4.9 per 1,000 per year, respectively (Dominguez and others 1980).

Host Factors

Until recently, humans were considered to be the only hosts and sources of M. *leprae* (Walsh and others 1977), but now there is evidence that armadillos are naturally infected with an organism which is indistinguishable from M. *leprae*. There is little evidence that these animals transmit the infection to humans, because armadillos are not found in areas of the world in which leprosy is hyperendemic.

That genetic factors as well as environmental factors have a role in the pathogenesis of leprosy is demonstrated by both twin and family studies which indicate that host genetics influence the type of disease that develops after infection (WHO 1985b).

Contact Status

The household contacts of persons with leprosy are at a greater risk of infection than nonhousehold contacts. And household contacts of those with lepromatous leprosy have a higher risk of infection than household contacts of those with nonlepromatous leprosy. A study conducted in the Philippines found that the attack rate in nonhousehold contacts was 0.83 per 1,000 person-years of observation. In contrast, incidence rates in household contacts of nonlepromatous and lepromatous cases were 1.6 and 6.23 per 1,000 person-years of observation (WHO 1985b). A similar study in Myanmar found that the cumulative incidence among nonhousehold contacts was 5.9 per 1,000 population per year and 21.9 per 1,000 per year among household contacts of lepromatous cases. For borderline cases it was 10 per 1,000 per year and for indeterminate and tuberculoid cases it was 7.6 per 1,000 per year (Lwin and others 1985).

Leprosy has been generally associated with poverty, and crowding may facilitate transmission (Noordeen 1985). Economic development has been proposed as a reason for the decline of leprosy prevalence in Europe and Japan. Consistent with this hypothesis is the twenty-year lag in the decline of leprosy (relative to the rest of the country) that was observed in the Okinawa prefecture in Japan, which had the slowest rate of economic development in the country. These shifts in risk factors appear to occur independently of any leprosy control activity, because they have been observed in countries with strict or relaxed isolation policies and in the absence of any other control measures. Once the situation is reached in which each new lepromatous case fails to produce, on average, one new secondary lepromatous case, the capacity for endemic persistence is broken, and disease incidence will gradually decline and ultimately reach zero (WHO 1985b). This process has important implications for leprosy intervention programs in endemic areas.

Physiological Factors

Claims have been made that puberty, menopause, pregnancy, lactation, stress due to infections, and malnutrition favor the onset of leprosy or lead to deterioration of a patient's clinical condition. These factors need to be studied in more detail to gain further information. Recent studies in Ethiopia suggest that there is a relationship between pregnancy and the onset or reactivation of the disease (WHO 1985b).

Current Prevalence and Trends

Estimating the number of leprosy cases in the world is a difficult task because the projections have to be based on the registered cases. These data may not be kept up to date, may contain misdiagnosed cases, and may be affected by incomplete reporting. With consideration of these potential inaccuracies, it has been estimated that the prevalence of leprosy in the world is 5.5 million cases. The geographic distribution of cases in the six WHO regions is shown in appendix 12A, table 12A-1. Of the 3.7 million registered cases in all the WHO regional areas, Southeast Asia has the largest estimated number of patients, 2.7 million. In this region, the majority of the cases (2.5 million) are in India.

There is no uniform distribution of either the disease itself or the various clinical forms. At the subcontinental level, the following patterns are recognized (WHO 1985b; see table 12A-1)

- *Tropical and subtropical belt of Africa and southern Asia.* This is considered to be the original source of leprosy; in these areas the disease can be traced back at least 2,500 years and remains endemic today.
- *Mediterranean basin.* Leprosy has probably been present in this region for 2,000 years, and still persists today, although prevalence of the disease is low and declining.
- *Northern Europe.* Leprosy was widespread in this area 1,000 years ago, reaching as far north as the Arctic Circle; however, from the thirteenth century, the prevalence of the disease has declined progressively. The decline observed in some populations of North America is in some ways comparable to the decline that occurred in northern Europe.
- *South and Central America.* Leprosy was introduced into this region from Europe and Africa, and the disease remains endemic today, although the incidence is declining in Venezuela.
- *Pacific Islands and Australia.* Leprosy has been introduced into several island populations during the last 200 years, and in some instances epidemics have occurred that have lasted for several decades.

The lepromatous proportion of cases (as estimated from case registries) also differs from region to region. In Europe this proportion is 20 percent, whereas in Sub-Saharan Africa it is 5 percent. In northern Asia it is between 5 and 20 percent (WHO 1985b). These differences may be the reflection of genetic, environmental, and cultural differences in the host populations. Diagnostic and reporting practices may also help explain the variation in the lepromatous proportion. The immunoepidemiologic studies conducted in Sri Lanka show that 5 percent of the total household contacts studied had

antibodies to phenolic glycolipid antigen, which is produced by M. *leprae*. In the hyperendemic community of Micronesia, approximately 10 percent of the population have been found to have this antibody (WHO 1985b).

In endemic areas, the prevalence of leprosy is maintained at a relatively constant level. During the past century, however, increases in the prevalence of leprosy have occurred in some areas of the world according to a distinct temporal pattern.

In Nauru, Ponape, and Truk, Hawaii, Irian Jaya, and eastern Nigeria, leprosy epidemics have been reported with prevalence proportions of 10 to 30 percent. These epidemics have appeared in communities in which leprosy has been introduced only recently and where environmental factors favor the rapid spread of infection. The epidemics are characterized by a rapid increase in the incidence of paucibacillary disease and a very low initial incidence of multibacillary leprosy, little clustering among household contacts, and fairly equal distribution of cases by age. Incidence reaches a peak and is followed by a fairly rapid spontaneous decline (perhaps attributable to the infection of all susceptible individuals). During this decline the proportion of multibacillary forms of the disease increases, a shift is seen toward a higher incidence in children, and there is increased disease clustering among household contacts. Gradually the conventional pattern of endemic leprosy emerges (WHO 1985b).

Irgens and Skjaerven (1985) report that epidemiologic surveillance in Norway, the United States, Nigeria, Japan, Venezuela, India, and China, covering periods from 1851 to 1981, has indicated a consistent decline in incidence rates of leprosy. At the same time, the age at onset, the ratio of male cases to female cases, and the proportion of multibacillary cases have been increasing. The increasing age at onset may be attributable to postponement of infection to a later age or an increasing fraction of patients with long incubation periods or both. The increasing importance of long incubation periods is consistent with the shift toward multibacillary cases, in which the incubation period is longer than that in paucibacillary cases.

This mechanism was also reported during the decline of tuberculosis. Irgens and Skjaerven (1985) propose the general principle that an increasing fraction of new patients with long incubation periods, resulting in an increasing age at onset, should be expected in any disease in rapid decline which also has a long and varying incubation period. This theory offers a basis for assessment of secular trends.

Economic Costs

The indirect costs of an illness are all costs other than those for health care. As mentioned earlier, leprosy affects people in the prime of life, with peak incidence between ten and twenty years of age and again between thirty and fifty. As many as 16 percent (Myint, Htoon, and Shwe 1992) of those with the disease may have serious (currently grade 2) disability with concomitant loss of productivity. Thus, the indirect costs from loss of productivity might be expected to be significant.

The productivity loss due to deformity from leprosy in India was evaluated in a survey by Max and Shepherd (1989) of 550 leprosy patients randomly sampled from a rural and an urban area in the state of Tamil Nadu, India. Their analysis showed that elimination of deformity would raise the probability of gainful employment from 42.2 to 77.6 percent. The authors' extrapolation to all of India's estimated 645,000 leprosy patients with deformity suggested that elimination of deformity would raise productivity by $130 million per year. This amount is one-eleventh of India's entire official development assistance for all purposes from all sources in 1985 ($1,470 million).

In addition to the cost of loss of productivity, there are social costs associated with the loss of healthy life brought about by leprosy. These include (but are not limited to) the burden on family members of living with and caring for a disabled relative. The cost of these social consequences should be considered as part of the indirect costs of leprosy. Though they are not insignificant, these social costs are not readily calculable. They will vary from community to community and will be associated with the social and cultural values each society attaches to an individual's life.

The direct cost of an illness refers to the costs of medical care (paid by patients or society) to control or treat the illness. The direct costs of leprosy include the costs of drugs, drug delivery, supervision of drug delivery, laboratory facilities for diagnosis and for monitoring response to treatment, and reconstructive surgery and rehabilitation. The effectiveness of a control program depends greatly on adequacy of case detection, which in turn depends on the level of knowledge of health workers and members of the community. Therefore, the costs of case detection or screening efforts as well as training of health workers and education of the community must be included along with the direct costs.

Direct costs of leprosy have not been assessed systematically. Lechat and others (1978) tested the relative cost-effectiveness of current or potential control methods using a computer simulation model. The model has potentially serious limitations, however (Lechat 1981), and so will not be discussed further here. Wardekar (1968) found that the development of deformity results in increased use of medical care. Deformity thus adds to direct costs as well as indirect costs. In addition to the cost of medical care borne by the leprosy patient, wages lost while seeking care must also be considered as part of the direct cost. A more detailed discussion of costs and effectiveness of various control programs is presented in appendixes 12B–12G. The total cost of a leprosy control program is estimated in appendix 12H.

Prevention Strategy

Though leprosy has plagued humankind for centuries, gaps in knowledge about the disease still exist, especially with regard to the natural history of disease and transmission. Even though great advances have been made in the microbiology, immunology, epidemiology, and treatment of leprosy during the past two decades, from 1966 to 1985 there was a 90 percent increase

in the number of registered cases. But more recently, from 1985 to 1990, the number of registered cases has declined by more than 30 percent. This decline has been attributed to the implementation of multidrug therapy and the consequent release of large numbers of patients from treatment. Multidrug therapy is also thought to increase the proportion of patients who present at an early stage of the disease, and thus it has a role in preventing and reducing the number and degree of deformity among new cases (Noordeen, Bravo, and Daumerie 1991) The risk factors and the primary prevention measures employed in leprosy control are presented in table 12A-2.

Leprosy is a disease with high infectivity but low pathogenicity and virulence. At present no specific primary preventive measure has been devised, and until this occurs, the main strategy for the prevention of leprosy must be early diagnosis and adequate and regular treatment.

Behavior

Many studies on social factors influencing leprosy have shown that it is a disease affecting the lower socioeconomic classes and that poor nutrition, sanitation, and personal hygiene, as well as overcrowding, are some of the factors which interact to influence persistence of the disease (Noordeen 1985). Improvement of economic conditions is beyond the scope of efforts to prevent leprosy. Still, any improvement of nutrition, sanitation, and personal hygiene through more broadly based health and education efforts should reduce the incidence of leprosy as well as that of a number of other diseases.

Environment

Lack of an adequate supply of clean water can lead to poor personal hygiene, which in turn may promote the transmission of leprosy, especially the skin contact mode of transmission. Though no supportive evidence has been presented for this theory, it is conceivable that the improvement in domestic water supplies in communities in which leprosy is highly endemic may disrupt the chain of transmission.

The high incidence rate among household contacts of leprosy cases may be attributable to overcrowding (Noordeen 1985). If droplet spread of infection does, in fact, occur in leprosy transmission, it is feasible that it might be facilitated in close quarters. Dealing with overcrowding is best done through a multisectoral approach involving population control, economic development, education, and health care services. Leprosy control would be only one of the many benefits of such a strategy.

Immunization

Several follow-up studies of the efficacy of BCG (bacille Calmette-Guérin) vaccine for the prevention of leprosy have been conducted. These studies have consistently found a protective effect of BCG against leprosy, but the vaccine effectiveness ranges from 80 percent in Uganda (Stanley and others 1981) to 20 percent in Myanmar (Lwin and others 1985; see table 12A-3). In a recent case-control study conducted in Tamil Nadu, India, researchers found that BCG vaccine appears to increase the risk of indeterminate leprosy while offering 61 percent protection against borderline disease (Muliyil, Nelson, and Diamond 1991).

The wide range of effectiveness has been attributed to different vaccine strains, regional and racial differences, and the prevalence of environmental mycobacteria. Despite the large number of studies of the subject, however, the effectiveness of BCG vaccine for leprosy control is still not well understood. The cost per dose of BCG is approximately $0.05 (UNICEF 1991).

A combination of killed *M. leprae* and BCG vaccine was used for the treatment of borderline lepromatous and lepromatous patients in Venezuela (Convit and others 1982) with promising results. Recently Talwar and others (1990) have found that lepromatous patients given a combination of multidrug therapy and a candidate antileprosy vaccine based on *Mycobacterium w* show distinctly better clinical improvement. Such observations that vaccines may be effective even when given after infection has occurred may revolutionize control efforts in many endemic communities.

Even if BCG is only 30 percent effective in preventing leprosy, as was reported from southern India and Myanmar (Noordeen 1983; Lwin and others 1985), this is good news for leprosy control, because the 30 percent reduction would be a spillover benefit from tuberculosis control programs already in place. This spillover benefit is another reason to support BCG vaccination in childhood immunization programs. Further studies must be conducted to determine the optimal age for vaccine administration for protection against both tuberculosis and leprosy. Because these two diseases have different incubation and exposure periods, a single dose of vaccine, which is sufficient to prevent tuberculosis, may not be sufficient to prevent leprosy. (See appendix 12E for discussion of the cost issues involved in immunization.)

With use of recombinant DNA techniques, it may be possible in the near future to develop a multivaccine which is effective against both leprosy and tuberculosis. It will be necessary, however, to learn more about the antigens relevant to protective immunity. Katoch and others (1990) review recent progress in applying advances in molecular biology of *M. leprae* to the problem of vaccine development. Several trials of vaccines against leprosy are currently planned or under way.

Health Education

Education regarding leprosy should be directed toward two different groups: first, leprosy patients and their immediate family, and second, the community. The nature of the educational material should also be different for these two groups because the message or aim of the education program in each case is different. Leprosy patients should be thoroughly educated about the nature and natural history of the disease. Certain age-old beliefs should be delicately handled, as they

may not be easily dispelled. The importance of regular compliance with prescribed therapy should also be stressed. Education of leprosy patients should be an ongoing process, and although it is time consuming, it should not be neglected. Failures in treatment with dapsone in the past have been attributed to neglect of patient education, although it is hard to pinpoint the number of relapses attributable to lack of health education.

Education to prevent injury in patients with nerve damage may reduce the loss of productivity which is so costly in leprosy. The patient's role in preventing permanent injury to hands and feet can be significant if he or she is taught to avoid activities that may potentially cause injury, to inspect anesthetic tissue regularly, and to practice early and correct wound care. Similarly, patients should be taught to prevent the opthalmologic complications of leprosy by avoiding eye dryness and protecting the eyes from injury (Watson 1988).

Educating the immediate family and the community is also necessary, especially in highly endemic areas. This will promote the early diagnosis of cases by making the community more aware and accepting of the disease. The goal of the program would be to encourage patients to come forward and obtain treatment rather than being ashamed of and concealing their disease. This is important because through early diagnosis a significant reduction in permanent disability can be achieved (Lechat 1985). Another goal of the health education effort is to dispel social stigmas through promotion of understanding of the disease. This will encourage a social environment in which the leprosy patient is treated in the same way as a person with any other disease. This social support is necessary if the leprosy patient is to lead the socially and economically productive life to which he or she is entitled according to World Health Assembly resolution WHA30.43.

Education of the community should be conducted as part of a general health education program. Education of persons with leprosy and their families should be a regular part of treatment. Although including education in treatment programs will add to their cost, the costs of neglecting education must also be considered. In the past, leprosy control programs which neglected education had limited effectiveness because of social discrimination, poor drug compliance, and lack of openness in dealing with the disease (Lechat 1985).

Treatment

If modern chemotherapy is to be of any help to leprosy patients, early diagnosis is crucial. It is important that cases be diagnosed before deformity has occurred so that they may be cured without leaving behind residual signs of this stigmatizing disease. Early case-finding activity must be promoted by leprosy control programs. Case finding may be passive or active. Passive case finding happens when patients come on their own to obtain treatment. It is greatly improved by increasing the accessibility of health care and also by promoting health education. A drawback of relying on passive case finding is that persons who are motivated to seek treatment on their own usually have advanced disease and are already disabled. Such advanced cases have also acted for some years as a source of infection in the community. Active case finding usually involves screening of schoolchildren, contact surveillance, and mass population screening activities (Lechat 1985). Preemployment screening of workers and military recruits may also be done but is usually not of much significance in leprosy control.

At present there is no specific screening test for leprosy which can discriminate an active from an inactive case with certainty (the current status of serological techniques in the epidemiology of leprosy is reviewed in Bharadwaj and Katoch 1990). Screening is based on clinical examination. This requires special training of health workers and is an expensive, time-consuming activity. The advantage of a well-conducted screening program is that cases are usually detected in their early stages. Because screening is costly, WHO has laid down guidelines for countries in which prevalence of leprosy is low (less than 1 per 1,000 population) and resources and personnel are lacking. In these countries, WHO recommends focusing only on surveillance of household contacts of lepromatous cases for a minimum of ten years after the index case is bacteriologically negative and on surveillance of household contacts of nonlepromatous cases for five years from the time of diagnosis of the index case. If these tasks prove impossible, it is recommended that contacts be examined at least once (WHO 1977).

Mass population screening programs are cost-efficient only in highly endemic communities and require careful planning and teamwork so that at least 95 percent of the population is covered. Without such high coverage the program may be unsuccessful, because those who are unwilling to come forward to be treated will continue to act as reservoirs of infection (WHO 1980; see appendix 12E for further discussion of the cost issues involved in screening).

Because most of the control programs in developing countries employ paramedical health workers for leprosy diagnosis at the village level, diagnostic criteria are needed which are simple and easily taught. The World Health Organization's four cardinal signs are useful for this purpose, although they may not be highly sensitive or specific. These four criteria are (a) a hypopigmented or hyperpigmented patch or macule, (b) an enlarged hard or tender nerve, (c) anesthesia in the area of the skin lesion, and (d) a positive skin smear. At least two of the first three criteria must be present.

With the introduction of more effective multidrug therapy, the cost of treatment per case has increased. Outlay of funds for drugs in specific control areas will also depend on the specificity of the health workers' diagnosis. Training of health workers thus improves the cost-effectiveness of treatment.

In the future, if diagnostic tools such as the polymerase chain reaction (PCR) technique are perfected, earlier and more rapid diagnosis of leprosy may be possible. At present, however, PCR is not easy to adapt to field conditions for several reasons, including the required use of radioisotopes and the expense of setting up the technique (Bloom 1990). Gillis and Williams

(1991) review possible uses of the PCR technique for studying leprosy.

Good Practice and Actual Practice

Treatment of leprosy is designed to render infectious patients noninfectious. Because there is no known animal reservoir for the disease, the chain of transmission could be interrupted if infectious cases in the community were made noninfectious through adequate and regular treatment. The chances of achieving control are greatly increased when at least 90 percent of the estimated multibacillary (infectious) cases are registered and treated regularly (WHO 1980). Historically, failure of many control programs in hyperendemic countries has been attributed to poor coverage and inadequate and irregular treatment of multibacillary cases. The number of new unregistered multibacillary cases is thus a useful indicator of continued transmission (WHO 1980).

As mentioned previously, a decline in the prevalence of leprosy has followed the introduction of MDT. Although MDT is thought to have led to a reduction in the number and degree of deformities among new cases, it does not completely prevent the reactions which lead to deformity (Noordeen, Bravo, and Daumerie 1991; Cellona and others 1990). The increasing acceptance of MDT among national health services and leprosy patients themselves is due to the fixed and relatively short duration of treatment; the low levels of toxicity and side effects; low relapse rates following completion of treatment; and the reduction in frequency and severity of erythema nodosum leprosum reactions (Noordeen, Bravo, and Daumerie 1991). Effective coverage of patients with MDT differs widely from country to country (Declercq and Gelin 1991), although on average it had reached 56 percent by October 1990 (Noordeen, Bravo, and Daumerie 1991).

The mode of delivery of treatment depends on the available resources, caseload, communication, manpower, and the type of drug schedule used. Two types of delivery used in hyperendemic countries are domiciliary treatment and stationary clinic treatment. Domiciliary treatment results in high coverage but is very costly, especially when supervised, because treatment with rifampicin and clofazimine must be given at least once a month. With domiciliary treatment, the delivery cost may outstrip available resources. In the latter case, the service area of the treatment program may have to be reduced, with rotation to a new area after completion of a minimum of two years treatment, or the program may have to be operated through a stationary clinic open at fixed times on fixed days of the week.

Treatment of locally endemic disease was one of the goals set for primary health care by the World Health Organization at the 1978 conference at Alma Ata. As a result of this recommendation, vertical leprosy control programs were dismantled in favor of integration of leprosy control into primary health care programs. The expectation was that with more personnel working in leprosy control, case finding would improve. In practice, however, because of the social stigma attached to leprosy, primary health care workers are often not highly motivated to work with leprosy patients, and case finding and management have suffered. This experience shows that training of primary health care workers should include education about leprosy and encouragement of the workers to take a more active role in case finding and management.

Because primary health care workers are not specifically trained to diagnose leprosy patients, they may be inaccurate diagnosticians. In particular, if their diagnoses are not highly specific, drugs and other resources will be wasted on patients who are false positives. In addition, patients who are falsely diagnosed will undergo unnecessary psychological stress. Therefore, it is important that primary health care workers be trained to improve their diagnostic skills and that the training be repeated at regular intervals to maintain a high level of diagnostic accuracy.

With the integration of leprosy control activities into primary health care programs, other activities such as WHO's Expanded Programme on Immunization compete with leprosy control for health care workers' time. In countries where leprosy is hyperendemic and resources are limited, the role of leprosy control may be reduced to drug delivery activities alone. Active case finding may have to be neglected, which will in turn result in a greater number of new cases with disability. The cycle of disability, social stigma, economic losses, poor treatment compliance, and further development of disability would then be perpetuated as in the days of dapsone monotherapy. Another danger is that poor compliance may lead to resistance to the newer drugs, as it did for dapsone monotherapy (WHO 1982).

Case Management

Treatment of leprosy is simple in the sense that there are very few alternative choices of drugs, but successful treatment is actually difficult. Often, case management has been simply equated with issuing patients the necessary drugs. But the psychological and social aspects of the disease must not be overlooked by health care workers, though this kind of comprehensive care can be difficult when caseloads are high. Health workers are often not trained to tackle the complexity of the problems leprosy presents. Failure to treat the leprosy patient as an individual in a comprehensive manner has often resulted in high treatment failure rates in countries in which leprosy is a significant problem. This high failure rate has also been attributed to the long duration of therapy. In the days of monotherapy with dapsone, paucibacillary patients were usually on a daily dapsone dose for five to seven years, and multibacillary patients were frequently on a daily dose for their lifetime. Lapses in compliance were common with such a long course of treatment, especially when unsupervised. This problem was further compounded by the irregular distribution of drugs by health care workers.

In the past, despite uneven patient compliance, treatment was often continued indefinitely because of the possibility of relapse. This resulted in great demand on leprosy clinics and

control workers and precipitated a decline in the quality of treatment (WHO 1982).

Many control programs continue to have high dropout rates. A number of investigations have indicated that even the patients who collect the drugs regularly from leprosy clinics do not necessarily ingest them. Researchers of earlier studies in Malawi (Ellard and others 1974) and Myanmar (Hagan and Smith 1979) used urinary analysis to monitor the regularity of dapsone self-administration. They found that not more than 50 percent of the outpatients had taken the prescribed dose in the three days prior to attendance.

This irregular treatment is suspected of having been the main reason for the development of dapsone resistance. In 1981 it was estimated that the prevalence of dapsone resistance for all of Malaysia was as high as 10 percent of all treated multibacillary patients (WHO 1988b). The secondary dapsone resistance in India was estimated at 23 per 1,000 multibacillary cases in 1978 and in Jiengsin Province, China, it was 51 per 1,000, compared with 35 to 40 per 1,000 multibacillary cases in Shanghai (WHO 1982). Pearson and his colleagues (1977) reported an even more disturbing situation in Ethiopia. The resistance proportion was found to be 190 per 1,000. Along with reports of secondary dapsone resistance from all over the world, primary dapsone resistance has been reported in Ethiopia, India, the Philippines, and Malaysia (WHO 1982).

Fortunately, the effectiveness of the multidrug alternative to dapsone monotherapy has been quite encouraging. Boerrigter, Ponnighaus, and Fine (1988) found a relapse rate of 4.17 per 1,000 person-years among paucibacillary cases treated with the multidrug regimen recommended by WHO, as compared with 12.9 per 1,000 person-years observed by Jesudasan, Christian, and Bradley (1984) among cases treated with dapsone alone. The World Health Organization (Noordeen, Bravo, and Daumerie 1991) has recently reported a relapse rate of 0.10 percent per year for paucibacillary patients and 0.06 percent per year for multibacillary patients.

In a three-year assessment of multidrug therapy in India by Ganapati, Revankar, and Pai (1987), it was observed that out of an initial 253 persons with multibacillary leprosy who were treated, 67 percent were smear negative after twenty-four doses (two-year standard WHO regimen) and 75 percent were smear negative after thirty-six doses. In the same study, 18 patients who were smear positive at the end of the two-year multidrug treatment were observed without further treatment; it was found that 17 of them went on to become smear negative within two years. This study showed that multidrug therapy has a distinct advantage over dapsone monotherapy and is an effective regimen for both individual treatment and public health intervention.

In a follow-up study of 129 persons with paucibacillary leprosy who were treated for one year with the multidrug regimen recommended by WHO, Ramanan and others (1987) found that 83.7 percent had clinically active leprosy at the end of the year of treatment. Further studies are necessary to determine whether it is advisable to continue treatment of those with paucibacillary leprosy beyond the recommended six months. A study by Neik and others (1988) found that 53 percent of those with multibacillary leprosy who were treated with the multidrug regimen recommended by WHO were rendered smear negative within two years and 94 percent within four and one-half years.

Unless new developments in vaccine production occur within a few years, there is little reason to expect that there will be a change in case management in the next decade. Any uncontrolled trial of a vaccine, of chemotherapy, or of a chemoprophylaxis program in a population that is beginning to undergo a "natural" shift in risk factors is bound to appear a success, although slowly. Even a controlled trial that alters environmental or host factors may not show rapid changes in subsequent incidence rates for the population because of the additional effects accompanying the natural decline described above. There is a minimum incubation period for leprosy, but the maximum interval from primary infection to disease onset may be as long as a lifetime. Thus cases may continue to appear for many years after the effective cessation of transmission, unless it becomes possible to eradicate the residual bacilli in all infected persons (Dharmendra 1986).

The case management strategy for leprosy can be divided into four categories.

- Treatment of leprosy
- Treatment of complications of leprosy
- Reconstructive surgery
- Psychological therapy and rehabilitation

Each category presents a unique treatment problem and must be tackled at different stages of the disease process. Case management interventions for leprosy are summarized in table 12A-4.

The primary and secondary level of management facilities should be general health care facilities that are already established in the community. This is important not only from the economic and feasibility aspect but also from a psychological standpoint. Separate facilities for the treatment of leprosy add to the isolation and stigmatization of patients with this disease.

Treatment of Leprosy

The treatment of leprosy with multidrug regimens serves four purposes. First, it interrupts the chain of transmission in the community by rendering infectious cases noninfectious. Though multibacillary cases may have infected others prior to treatment, one can assume that once they are treated, their role in the transmission of the disease has been diminished. Second, it cures patients of the disease. Third, it prevents the emergence of drug-resistant strains in the future. Last, it halts the disease process, and if the disease is treated in its early stage, it will prevent further development of deformity.

Treatment regimens for leprosy are considered separately for paucibacillary and multibacillary cases. Paucibacillary leprosy includes indeterminate and tuberculoid cases in the Madrid

classification (WHO 1980) and I, TT, and BT leprosy in the Ridley and Jopling classification (Ridley 1977), whether diagnosed clinically or histopathologically. The bacteriological index must be less than two at any site (according to the Ridley scale [WHO 1982]). The World Health Organization has recommended a short course of therapy for paucibacillary cases with 600 milligrams of rifampicin once a month for six months to be given under supervision along with 100 milligrams of dapsone (1–2 milligrams per kilogram of body weight) daily for six months. The cost of drugs for the six-month course of treatment for a paucibacillary case is $2.15. It is estimated that the cost of delivery of the drugs is $4.50 and the cost of supervision of drug delivery an additional $1.35, bringing the total cost to $8.00 (see appendix 12C for details).

It is recommended that if treatment is interrupted, the regimen should be started again where it was left off and the full course completed. If relapse occurs after termination of treatment (release from control or discharge), the same treatment is to be restarted (WHO 1980).

Multibacillary leprosy includes both lepromatous and borderline leprosy in the Madrid classification (WHO 1980) and LL, BL, and BB leprosy in the Ridley and Jopling classification (Ridley 1977). The regimen recommended by WHO for a multibacillary case is 600 milligrams of rifampicin and 300 milligrams of clofazimine in a single dose once a month to be given under supervision along with 100 milligrams of dapsone and 50 milligrams of clofazimine daily to be self-administered. This treatment is to be followed for at least two years and is to be continued wherever possible until the patient achieves skin smear negativity (WHO 1988). The average duration of treatment for multibacillary cases should be about three and one-half years (S. K. Noordeen, Chief Medical Officer, Leprosy, Division of Communicable Diseases, WHO, personal communication August 30, 1989). The cost of drugs for a course of treatment of three and one-half years for a multibacillary case is $81.66. The cost of delivery is estimated at $31.50, and supervision of delivery is an additional $9.45, bringing the total cost of treatment to $122.61 per case. Considering that approximately 20 percent of cases are multibacillary and 80 percent are paucibacillary, the average cost per case is $30.92, a weighted average (see appendix 12C for further discussion).

The case management strategy outlined above should be implemented at all the four levels of management, namely household, primary, secondary, and tertiary. Apart from surgical care, both diagnostic and medical care should be provided at these four levels but at different levels of sophistication.

At the household level, simple diagnostic procedures should be performed by primary health care workers and the necessary drugs should be distributed if resources are available. At the primary management level, both diagnostic and medical treatment should be made available, especially when lack of resources prevents delivery of services at the household level. Even in instances in which household care could be provided, care at the primary level is still necessary for supervision and monitoring of therapeutic response and also in circumstances in which second-line drugs, such as ethionamide or protionamide, must be introduced.

The role of the secondary level of management in the treatment of leprosy is limited and should be mainly concerned with treatment and diagnosis of the side effects of the multiple drug regimens (such as sulfone allergy to dapsone and liver toxicity from rifampicin) which are being prescribed in the catchment area of that facility. The tertiary level of management should be concerned with research and development of new drugs and treatment procedures and monitoring of drug resistance and side effects.

Treatment of Complications

Two types of reactions occur in leprosy patients. Type I reaction, which is seen commonly in cases of the tuberculoid spectrum, is the most serious type of the two because the patient may suffer from severe nerve damage within days and needs immediate referral, prompt care, and in some cases even hospitalization. Type II reaction, which is also known as erythema nodosa leprosum (ENL), is seen in the lepromatous spectrum of cases. Although it does not give rise to nerve damage immediately, ENL is an important clinical problem because patients may suffer from repeated episodes, which may cause a loss of confidence in the treatment regimen.

Reactions are only occasionally medical emergencies, although type I reactions require urgent action because of the potential for nerve damage and deformities. The most effective treatment at present for both types of reactions is prednisolone, which should be given in a very high dose, as much as 20 to 80 milligrams per day, to be slowly reduced, depending on the clinical response, to a daily maintenance dose of 5 to 10 milligrams. The duration of treatment varies from patient to patient. The daily prednisolone requirement may be discontinued within two to three months or continued for more than two years. Other general supportive therapy such as analgesics and sedatives, along with adequate rest and nutrition, is also important (WHO 1980).

Thalidomide has proven effective for ENL cases, with few toxic effects. But its known teratogenic effect prevents widespread use in the field from being a feasible option even though the drug is relatively inexpensive (WHO 1980). Clofazimine in a 200 to 300 milligram daily dose has an anti-inflammatory effect, but it takes four to six weeks to exert its effect and is toxic if used for long periods (Jacobson 1985). Its use in the treatment of reactions is limited to severe cases, but if used together with prednisolone it may lower the daily requirement of the latter.

Ulcers, another complication in leprosy, are a consequence of anesthesia occurring in the extremities due to peripheral nerve damage. Once the peripheral nerves have been damaged, nothing can be done to reverse the damage. Care of the anesthetic extremity becomes extremely important for the prevention of ulcers. The precipitating cause of ulcers are burns, mechanical pressure, and accidental injury to the hands and feet. The most effective way to treat ulcers is to immobilize

or rest the affected part of the extremity. Antibiotics, along with surgical dressing, will also shorten the course of the ulcer.

Treatment of mild nerve damage and ulcers may be undertaken at the household level with frequent visits to the health care facility for necessary drugs and supervision. If a reaction is severe, with signs of nerve compression, the patient should be referred to a secondary facility. Ulcers complicated by osteomyelitis will require surgical intervention, which may be obtained by referral to a secondary-care facility. Tertiary care may be needed in some few cases in which reactions cannot be controlled or if osteomyelitis and osteoarthritis have become so advanced that amputation is necessary.

Reconstructive Surgery

Because reconstructive surgery is expensive and is not important for control of leprosy, it has been neglected by many control programs. But reconstructive surgery is very important for the social and psychological well-being of the patient. Correction of various deformities will also increase the economic productivity of leprosy patients. A further consequence is the promotion of trust in the health care system, and along with it, drug compliance.

Reconstructive surgery must be obtained in highly specialized tertiary-care facilities with a staff of reconstructive surgeons. The direct benefits in dollars are hard to estimate, especially when self-esteem and happiness are the greatest benefits of these procedures. Reconstructive surgery is required in 2 to 5 percent of all cases (Myanmar, Ministry of Health 1985).

Psychological Therapy and Rehabilitation

It is well known that many leprosy patients suffer from psychological and social problems. Many control programs focus their efforts on drug distribution and treatment of complications and pay little attention to the psychological and social problems of the patients. This lack of attention may be contributing to high dropout rates. Primary health care workers are normally not trained to provide psychological or rehabilitation services, but they should at least be trained to identify problem cases and refer them to secondary referral facilities.

Rehabilitation in leprosy involves the combined and coordinated use of medical, social, educational, and vocational measures for training or retraining the individual to the highest possible level of functional ability. The surest and least expensive rehabilitation is to prevent physical disability, which is done through patient education about self-care and through early diagnosis and treatment by clinicians. Rehabilitation must begin as soon as the disease is diagnosed (WHO 1980). Rehabilitation activities include:

- Health education of the public so as to reduce prejudice against the disease.
- Vocational training, which may be given in an institutional setting or on a part-time basis. Such training should not disrupt the patient's life.
- Prevention of disabilities by simple methods that can be applied in the field, such as simple forms of physiotherapy, provision of special footwear and crutches, and the teaching of patients to avoid injury and, when it occurs, to attend to it early (Watson 1988).

Priorities for Operations Research

As mentioned in the section on prevention, more research is necessary to understand the variability in the efficacy of BCG vaccine for the prevention of leprosy and to develop a more effective vaccine. Preliminary research has indicated that certain vaccines against leprosy used in combination with MDT as immunotherapeutic agents appear to be effective in the treatment of leprosy patients. More studies are needed to evaluate these findings. In addition, the sensitivity analyses presented in appendix 12D indicate that further efforts are necessary to determine more precisely the reduction in permanent disablement brought about by treatment of complications. Additional research that should be done includes study of the mechanism of transmission, incubation period, sensitivity and specificity of diagnosis by various methods, and the morbidity risks associated with early lesions of different types. Development of drugs that act faster than the current ones should also be investigated and the effectiveness of intervention programs determined.

Priorities for Resource Allocation

The application of basic concepts and principles of economic analysis and management science suggests that early diagnosis and adequate and appropriate treatment should be given the highest priority in leprosy control. Current projections indicate that a 60 to 80 percent reduction in the prevalence of leprosy may be achieved within five to seven years with widespread use of MDT (Noordeen, Bravo, and Daumerie 1991). Even if such a reduction in prevalence can be realized, disability in cured patients will still be a problem for many years. In addition, a continuing slow trickle of new cases (infected many years earlier) can be expected because of leprosy's long incubation period. The second priority for resource allocation should thus be research, with emphasis on development of a vaccine effective in preventing transmission and development of drugs with quicker action. Finally, resources should be allocated to prevention and treatment of disability in patients with nerve damage.

Conclusion

It is our conclusion that the benefits of leprosy control programs have been underestimated in the past and that the effect

of the disease is significant in many developing countries. Studies of the currently recommended multidrug therapy program have found that it is effective in controlling leprosy. Furthermore, the cost-effectiveness analysis presented in this chapter indicates that the cost per year of healthy life gained (YHLG) from implementation of this regimen is quite low. Ranking leprosy control on a list of health care priorities will, of course, depend on its comparison with intervention programs for other diseases. Still, we urge the priority setters to consider the significant intangible benefits of a leprosy control program as well as the cost per YHLG presented here.

Appendix 12A. Tables

The tables below summarize incidence and risks of leprosy and its prevention and management.

Table 12A-1. Registered Leprosy Cases, by WHO Region

WHO region	Prevalence (per 10,000)	Incidence (per 10,000)
Africa	9.2	0.71
Americas	4.2	0.42
Southeast Asia	20.5	3.72
Europe	0.1	0.00
Eastern Mediterranean	2.6	0.15
Western Pacific	1.0	0.09
Total	7.1	1.09

Source: Noordeen, Bravo, and Daumerie 1991.

Table 12A-2. Risk Factor and Points of Prevention for Leprosy

Risk factor/point of prevention	Mechanism	Relevance to leprosy
Behavior		
Personal hygiene	Transmission	Low
Environmental		
Domestic water	Transmission	High
Public health		
Immunization with BCG vaccine	Resistance to infections	Medium
Health education	Transmission	Medium
Treatment		
Early diagnosis	Transmission	High
Adequate and regular treatment	Transmission	High

Source: Authors.

Table 12A-3. BCG Vaccine Efficacy in Control of Leprosy

Area	Subjects	First year	Age at vaccination (years)	Vaccine used	Follow-up (years)	Vaccine efficacy (percent)	Source
Uganda	16,150	1960	0–10	Glaxo	8	80	Stanley and others 1981
New Guinea	5,000	1962	All	Japan	14	48	Bagshawe and others 1989
South India	210,337	1968	All	Paris and Copenhagen	5–10	23	Noordeen 1986
Burma	28,220	1964	0–14	Glaxo	11–14	20	Lwin and others 1985
Malawi	80,622	1979	0–15	Glaxo	Less than 5 years	50	Fine and others 1986

Table 12A-4. Case Management Interventions for Leprosy

Strategy	Level of Management			
	Household	Primary	Secondary	Tertiary
Secondary prevention or treatment	Diagnosis, medical	Diagnosis, medical	Diagnosis, medical	Diagnosis, medical
Treatment of complications[a]	Diagnosis, medical	Diagnosis, medical	Diagnosis, medical, surgical	Diagnosis, medical, surgical
Reconstructive surgery	n.a.	n.a.	n.a.	Diagnosis, medical, surgical
Psychotherapy and rehabilitation	n.a.	Diagnosis	Diagnosis, medical	Diagnosis, medical

n.a. Not applicable.

a. In many developing countries, the leprologists and plastic surgeons needed for treatment of serious complications are found only in tertiary facilities.

Source: Authors.

Appendix 12B. Cost-Effectiveness Analysis

A cost-effectiveness analysis will be used to evaluate the costs of a leprosy control program. Such an analysis differs from a cost-benefit analysis in that input (cost of the control program) is considered in monetary terms and output (benefits of the control program) is considered in nonmonetary terms, whereas in a cost-benefit analysis both input and output are considered in monetary terms. The results of a cost-effectiveness analysis might be expressed as cost per death averted or per year of healthy life gained rather than as a ratio of cost of the control program to savings resulting from preventing loss of productivity. This approach is useful when the goal is to compare the costs of alternative strategies to achieve certain health outcomes or to compare the expected effect of each dollar spent across different disease control programs, the latter being the goal here.

A Supercalc microcomputer spreadsheet model developed by Ralph R. Frerichs of the Department of Epidemiology, School of Public Health, University of California at Los Angeles, will be used to evaluate the cost-effectiveness of a leprosy control program. The model is based on earlier work done in Ghana by the Ghana Health Assessment Project Team (1981). The model output is direct cost per year of healthy life gained. No attempt is made in the model to quantify indirect costs (or savings from preventing indirect costs) in monetary terms. The cost per YHLG was calculated for two different components of a control program, that is, drug therapy and treatment of complications, first individually and then in combination. The parameters of the model are:

- Average age at onset (AO)
- Average life expectancy at onset (L)
- Average age at death for those who die of the disease (AD)
- Case-fatality proportion (CF)
- Proportion of disablement prior to death of those who die of the disease (DPD)
- Proportion of those who do not die of the disease but who are permanently disabled (CD)
- Average level of disablement of the permanently disabled (CDP)
- Temporary days of disability (T)
- Level of temporary disablement (TPD)
- Incidence (I)

These parameters are entered first for the situation in which no intervention is undertaken. Then the proportionate changes in these parameters after intervention are entered into the model. From these changes, the model calculates years of healthy life gained from the intervention. It is then a case of putting in the cost of the intervention and dividing it by the years of healthy life gained.

Parameters were estimated as follows, assuming no intervention. The estimates come from data for Myanmar or represent educated guesses arrived at by consensus of two of us (Htoon and Kosasih) who had experience treating leprosy patients in developing countries.

- *Average age at onset:* 29 years (taken from urban data in Yangon, Myanmar).
- *Average life expectancy (at age of onset):* 41.52 years (data for Myanmar males, WHO 1985a).
- *Average case fatality:* 0.001 (Walsh 1988).
- *Average age at death of those who die of the disease:* 39 years (educated guess).
- *Proportion of disablement prior to death:* 0.8 (educated guess); the proportion of disablement is proportionate reduction in functional ability.
- *Proportion permanently disabled:* 0.16 (Myint, Htoon, and Shwe 1990).
- *Proportion of disablement of permanently disabled:* 0.5.
- *Temporary disability days:* 30 days; temporary disability for leprosy represents days during which the patient has skin lesions and suffers the accompanying psychosocial consequences but has no physical disability (educated guess).
- *Proportion of disablement of temporarily disabled:* 0.05; it is assumed that during the period of temporary disability, the patient does not have full productivity because of the psychosocial consequences of the disease, but that his or her productivity is reduced only slightly, that is, by 5 percent, because there is no actual physical disability during this period (educated guess).
- *Incidence:* 3 per 1,000 per year in Myanmar (Burma, Ministry of Health 1985). For each case of the disease, the model calculates:

Days lost because of premature death (x1):

$$(1) \qquad x1 = CF \cdot [L - (AD - AO)] \cdot 365$$

Days lost because of disability before death (x2):

$$(2) \qquad x2 = CF \cdot (AD - AO) \cdot DPD \cdot 365$$

Days lost because of chronic disability among those who do not die of the disease (x3):

$$(3) \qquad x3 = CD \cdot L \cdot CDPD \cdot 365$$

Days lost because of temporary disability among those who do not die of the disease and are not permanently disabled (x4):

$$(4) \qquad x4 = (1 - CF - CD) \cdot T \cdot TPD$$

Total days of healthy life lost (DHLL) because of the disease is, then, the sum of these four parameters:

$$DHLL = x1 + x2 + x3 + x4$$

Total days of healthy life lost per 1,000 population is calculated by multiplying total days of healthy life lost by incidence per 1,000 population.

Then, considering an intervention, the days of healthy life gained (*DHLG*) per 1,000 population is calculated by the following formula:

$$DHLG/1{,}000 = DHLL/1{,}000 - [I \cdot PI \cdot (DHLL - DHLG)],$$

where *PI* is the proportionate change in incidence.

The model has been used to estimate the cost per YHLG for drug therapy and treatment of complications. Some specific limitations of the analysis presented below should be emphasized. The state of the leprosy literature precludes accurate estimation of the various parameters used as inputs in the model. Therefore, the numbers used represent "best estimates." No sensitivity analyses were done on these "before intervention" parameters. Sensitivity analyses were done, however, for the effects of the three components of the intervention. These analyses involve varying the value of uncertain parameters within an expected range to see how sensitive the output (in this case cost per YHLG) is to the changes in a parameter. Sensitivity analysis is useful in that it provides some information about the degree to which the estimate of cost per YHLG might be inaccurate as a result of our uncertainty about a parameter.

Appendix 12C. Cost-Effectiveness of Multidrug Therapy

The first analysis considers the costs and benefits of drug therapy alone. The drug regimens are those recommended by WHO for multibacillary and paucibacillary cases (see the section on case management). Prices are taken from UNICEF's *Essential Drugs Price List* for July through December 1991. As shown below, the cost of drugs to treat a paucibacillary case is $2.15. It is estimated that the cost of delivery of the drugs and supervision is an additional $5.85 (see below for calculation of delivery cost), bringing the total cost of treating a case to $8.00. The cost of drugs to treat a multibacillary case is $81.66. It is estimated that the cost of delivery and supervision is an additional $40.95, bringing the total cost of treatment to $122.61 per case. Considering that approximately 20 percent of cases are multibacillary and 80 percent are paucibacillary, the average cost per case is $30.92 (a weighted average).

This multibacillary-to-paucibacillary ratio of 20:80 is based on the 1988 *Annual Report of the Leprosy Control Program*, Ministry of Health, Burma. The ratio was estimated for a leprosy endemic area in which multidrug treatment is not in use. Because paucibacillary cases are to be discharged after six months of treatment, their number will be quickly reduced compared with the number of multibacillary cases, which require an average of three and one-half years of treatment. Only after some years of multidrug treatment will the multibacillary-to-paucibacillary ratio reach 50:50. The ratio will be even higher if the new case-finding activity is poor that discharged cases are not being replaced by an equivalent number of new cases. The cost per year of healthy life gained from treatment is calculated to be $12.71 per YHLG.

Details of the Calculations

Cost per case was first calculated separately for treatment of multibacillary and paucibacillary cases. The WHO treatment regimens and the calculation of costs per case (with use of the *Essential Drugs Price List*) were as follows:

- *Paucibacillary cases:* 600 milligrams of rifampicin once a month for six months. Rifampicin comes in 300-milligram tablets, so twelve tablets of 300 milligrams are needed.

$$12 \cdot \$9.87/100 = \$1.18.$$

100 milligrams of dapsone daily for six months. Approximately 190 doses are needed.

$$190 \cdot \$5.10/1000 = \$0.97.$$

The cost per case of delivering the drugs is estimated in the following way (from Myanmar, Ministry of Health 1985: the cost of delivery, including salaries and traveling allowances, is estimated at 4,664,000 kyats for 1985. At the exchange rate of 7 kyats to the U.S. dollar, this is equal to 4,664,000 divided by 7, or $666,286. The total number of cases treated in 1985 in Myanmar was 221,125. Thus the cost of delivery per case is $666,286 divided by 221,125, or $3 per case per year. This figure includes the cost of supervision, but not of vehicles, because the latter are to be considered as part of the capital cost. As endemicity decreases, the delivery cost is likely to go up. This $3 per case per year is calculated under the assumption of high endemicity and represents the cost for an average of four visits by health care workers. Six visits are needed for paucibacillary cases, however, so the cost of delivery for a paucibacillary case will be $3 · 6/4 = $4.50. The additional cost for supervision of drug delivery is estimated to be 30 percent of the delivery cost, or $1.35.

Thus, the total cost of drug therapy for a paucibacillary case is equal to

$$\$1.18 + \$0.97 + \$4.50 + \$1.35 = \$8.00.$$

- *Multibacillary cases:* 600 milligrams of rifampicin once a month for three and one-half years (Dr. S. K. Noordeen, Chief Medical Officer, Leprosy, Division of Communicable Diseases, WHO, personal communication August 30, 1989). Rifampicin comes in 300-milligram tablets, so 84 tablets (2 · 42) are needed.

$$84 \cdot \$9.87/100 = \$8.29.$$

300 milligrams of clofazimine once a month for three and one-half years. Clofazimine comes in 100-milligram capsules, so 126 capsules (3 · 42) are needed.

$$126 \cdot \$96.74/1000 = \$12.19.$$

100 milligrams of dapsone daily for three and one-half years, so 1,278 tablets (3.5 · 365) are needed.

$$1{,}278 \cdot \$5.10/1{,}000 = \$6.52.$$

50 milligrams of clofazimine daily for three and one-half years (except the forty-two days on which a 300-milligram clofazimine dose is taken), so 1,130 capsules (3.5 · [365 - 42]) are needed. A price is listed only for 100-milligram capsules, so this price will be halved for the calculation.

$$1{,}130 \cdot (\$96.74/2)/1000 = \$54.66.$$

The cost per case of delivering the drugs for a multibacillary case is estimated as above for paucibacillary cases. If it costs $3 per case for an average of four visits to deliver drugs in Myanmar, and if forty-two visits are necessary for a multibacillary case, the delivery cost for a multibacillary case will be $31.50 ($3 · 42/4). Thirty percent of the drug delivery cost ($9.45) will be added to cover the cost of supervision of drug delivery.

So the total cost of drug therapy for a multibacillary case is:

$$\$8.29 + \$12.19 + \$6.52 + \$54.66 + \$31.50 + \$9.45 = \$122.61.$$

Note: This may be an overestimate of cost for some multibacillary cases because treatment may be needed for only two years.

- Given that approximately 80 percent of cases of leprosy are paucibacillary cases, and 20 percent are multibacillary cases, the average cost of treating a leprosy case can be estimated by taking a weighted average:

$$(0.80 \cdot \$8.00) + (0.20 \cdot \$122.61) = \$30.92.$$

In the first analysis, the following initial assumptions were made (based on best estimates):

- That treatment of multibacillary and paucibacillary patients would reduce by 33 percent the proportion of patients who do not die but are permanently disabled and would reduce by 60 percent the level of disablement of these cases.

Table 12C-1. Cost-Effectiveness of Treatment Programs for Leprosy

Parameter	*Baseline*	*With interventions*	
		Drug therapy	*Complications*
Average case fatality	0.001	No change	No change
Annual incidence (new cases per 1,,000 population)	3.00	No change	No change
Average age at disease onset (years)	29	No change	No change
Average life expectancy at disease onset (years)	41.52	No change	No change
Average age at death from leprosy (years)	39	No change	No change
Proportion disablement of fatalities	0.8	No change	No change
Proportion of survivors permanently disabled	0.16	0.67	No change
Proportion disablement of permantly disabled	0.5	0.4	0.8
Temporarily disabled			
Days of temporary disability	30	0.67	0.8
Proportion disablement during period of temporary disability	0.05	No change	0.8
DHLL/DHLG *per case*[b]			
From premature death	11.50	0.00	0.00
From disability before death	2.92	0.00	0.00
From permanent disability among survivors	1,212.38	887.47	242.48
From temporary disability among survivors	1.26	0.36	0.45
Total	1,228	888	243
Total per 1,000 population per year	3,684	2,663	729
Costs of intervention			
Per case (dollars)	n.a.	30.92	225.00
Per YHLG (dollars)	n.a.	12.71	338.06

n.a. Not applicable.
a. Expected proportionate increase or decrease as result of multiple drug therapy and treatment of complications.
b. For baseline, days of healthy life lost. For intervention, days of healthy life gained from reduction of listed parameter.
c. Represents 98.72 percent of total DHLL per case.
Source: Authors.

- That treatment would also reduce the number of days of temporary disability by 33 percent.
- That treatment would not affect any of the other parameters of the model. (Eventually treatment of patients would reduce the incidence by decreasing the numbers of patients who are acting as sources of infection. This idea will be explored in the sensitivity analysis.)

In table 12C-1 we summarize the cost-effectiveness of treatment according to the model.

Results

The average cost of treating a leprosy patient (regardless of type of leprosy) is $12.71 per YHLG. It must be mentioned that the cost of laboratory facilities needed for confirmation of diagnosis and for determination of bacteriologic status of patients at the end of the course of treatment is not included in this calculation. Neither is the benefit of reduced incidence, which would come in time if the treatment program is maintained (although this will be discussed below).

Sensitivity Analysis

A sensitivity analysis was done to determine how much the cost per YHLG would be affected by varying the effects of drug therapy on the proportion of patients who are permanently disabled, the proportion of disablement of the permanently disabled, the temporary disability days, and the incidence. The first three parameters were varied to allow for inaccuracy in "educated guesses" regarding the effect of multidrug therapy on these parameters. The sensitivity analysis shows whether it matters that the estimates might be inaccurate. Variation in incidence is also explored because incidence will be reduced if a drug therapy program is continued for several years, and the cost per YHLG will subsequently be decreased (depending on the discount rate).

The sensitivity analysis involved the changes shown in table 12C-2 (values were varied for one parameter at a time). The model proved to be relatively insensitive to these changes. As might be expected, when the minimum values are entered for all the parameters (except incidence) and the resulting cost per YHLG is compared with the cost per YHLG in the situation in which all the maximum values are entered, there is little difference between the two outputs ($25.15 per YHLG as opposed to $10.34 per YHLG). Finally, in recognition of the possibility that costs may have been underestimated in the model, the cost per case was varied to determine the effect on the cost per YHLG. When the cost per case was doubled, the cost per YHLG for chemotherapy was $25.42, still a reasonable figure. Even when the cost per case was tripled, the cost per YHLG for drug therapy was only $38.13.

Table 12C-2. Effects of Drug Therapy on Cost per YHLG

Parameter	*Reduction (percent)*	*Cost per YHLG (dollars)*
Proportion premanently disabled	0.10–0.50	14.54–11.63
Disablement of permanently disabled	0.30–0.80	17.52–10.75
Temporary disability days	0.10–0.50	12.71–12.71
Incidence	0.30–0.70	12.71–12.71

Note: Values were varied for one parameter at a time.
Source: Authors.

Appendix 12D. Second Analysis: Treatment of Complications

In the second analysis we consider the costs and benefits of treating complications of leprosy, including treatment of reactions and ulcers, reconstructive surgery, and all forms of rehabilitation. Costs of treating the complications were estimated to be $225.00 per case by consensus of the two members of our group who had had experience treating leprosy patients in a developing country. It was further estimated that 10 percent of cases would have complications requiring treatment. The model calculates that it costs $338.06 per YHLG to treat the complications of leprosy. This makes the cost of the combination of drug therapy and treatment of complications $350.77 per YHLG ($12.71 per YHLG + $338.06 per YHLG), assuming there is no interaction between drug therapy and treatment of complications, which is a reasonable assumption. The cost of psychotherapy is not included in this analysis. Further details are provided below.

Details of the Calculations

- The cost of treating reactions with prednisolone was estimated to be $3 per case on average. The estimate is complicated by individual variation in clinical response. The duration of treatment may be as short as two to three months or longer than two years. Prednisolone is such an inexpensive drug, however, this wide variation in duration of treatment is not expected to be important.
- The cost of treating ulcers was estimated at $20 per case on average.
- The cost of reconstructive surgery was estimated at $200 per case, and the cost of rehabilitation was estimated at $2 per case.
- Therefore, the total cost per case of treating complications of leprosy was estimated to be:

$$\$3 + \$20 + \$200 + \$2 = \$225.$$

In the second analysis, the following assumptions were made (input and output of the model are shown in table 12C-1):

- That treatment of complications reduces the disablement of permanently disabled cases by 20 percent.

- That it reduces the days of temporary disability by 20 percent.
- That it reduces the disablement during temporary disability by 20 percent.
- That it does not affect any other parameters in the model.

Results

The cost per YHLG for treatment of complications was calculated to be $338.06. The cost per YHLG for drug therapy plus treatment of complications was thus $350.77 per YHLG ($12.71 per YHLG + $338.06 per YHLG), assuming no interaction between the two components of the control program.

Sensitivity Analysis

A sensitivity analysis was done to determine how much the cost per YHLG would be affected by varying the effects of treatment of complications on the proportion of disablement of patients who are permanently disabled, the temporary disability days, and the proportion of disablement of those who are temporarily disabled. These three parameters were varied to allow for inaccuracy of educated guesses of these values. Again, the sensitivity analysis shows whether it matters that the estimates might be inaccurate. The sensitivity analysis involved the changes shown in table 12D-1.

The model was sensitive to changes in proportion of disablement of patients permanently disabled, indicating that knowledge of the effect of treating complications is necessary to have confidence in the estimate of cost per YHLG given by the model. Changes in the temporary disability days and the disablement of the temporarily disabled have little effect on the output because initial values of these parameters are so low that even a 50 percent change in the values is a small amount. When the minimum values are entered for all the parameters, including incidence, and the resulting cost per YHLG compared with the cost per YHLG in the situation in which all the maximum values, including incidence, are entered, the same values are obtained ($676.05 per YHLG as opposed to $135.27 per YHLG).

Again, because costs cited in this analysis may have been underestimated, it may be useful to consider the output if the average costs of treating complications are doubled ($676.12 per YHLG) or even tripled ($1,014.18 per YHLG).

Table 12D-1. Effects of Treatment of Complications on Cost per YHLG

Parameter	*Reduction (percentage)*	*Cost per YHLG (dollars)*
Disablement of permanently disabled	0.10–0.50	674.86–135.38
Temporary disability days	0.10–0.50	338.20–337.64
Disablement of temporarily disabled	0.10–0.50	338.20–337.64

Source: Authors.

Appendix 12E. Cost Issues in Screening and Immunization

The cost per YHLG of a screening program was not considered in this analysis because the model used was not designed for this application. Additional parameters such as coverage of the population and sensitivity and specificity of diagnosis are needed if the model is to reflect the effect of a screening program. The cost aspect of the analysis is complicated by the fact that screening without treatment has no effect on disease control.

In lieu of a cost per YHLG measure of the cost-effectiveness of a screening program, some of the cost issues involved with screening will be discussed briefly. It was estimated (by the two members of our group who had experience treating leprosy patients) that the cost per person of screening by clinical exam would be approximately $0.10 (based on costs in Myanmar). The total cost of screening would then be calculated by multiplying the cost per person by the number of persons screened. Therefore, screening 1,000 people would cost $100. The number of cases that would be detected by screening (but that would have gone undetected without screening) would have to be considered. It was further estimated that a screening and treatment program would decrease age at onset by 10 percent, that it would decrease the proportion of cases who do not die but are permanently disabled by an additional 20 percent (over treatment alone), and that it would decrease the proportion of disablement of those who are permanently disabled by an additional 20 percent. The screening and treatment program would eventually decrease incidence because the cases would be caught and treated earlier, thereby shortening the period during which persons with the disease are transmitting it. Because some of the benefits of screening and treatment are future benefits, the cost should be discounted. The cost of screening programs is relatively high because many people who do not have symptoms of the disease must be screened so that the few who do have it are found. Thus, a screening program must be very effective to justify the cost.

The cost per YHLG of a vaccination program with BCG vaccine was not considered because the efficacy of BCG vaccine for leprosy prevention is so variable from area to area, and the appropriate vaccination schedule is still a matter of debate. Also, this cost would be shared by leprosy and tuberculosis control programs. The cost per dose of BCG vaccine is small (approximately $0.10 in developing countries, Walsh 1988), however, so prevention of even a small proportion of the expected number of leprosy cases might justify the use of the vaccine for leprosy control, especially when the efficiency of immunizing for both tuberculosis and leprosy is considered. Of course, delivery costs would have to be included in such an analysis.

Appendix 12F. Effect of Accuracy of Diagnosis

In the analysis of the cost-effectiveness of drug therapy (appendix 12C), perfect accuracy of diagnosis was assumed. In

this analysis, another spreadsheet program will be used to calculate cost per identified true case of the disease at varying levels of sensitivity and specificity of diagnosis. Inputs for this spreadsheet include the following:

- True prevalence among those who see a health worker: 10 per 1,000 (WHO 1985a)
- Sensitivity and specificity of diagnosis: to be varied.
- Cost per YHLG of multidrug therapy: $30.92 as calculated in previous model

Outputs (table 12F-1) include the following:

- Prevalence of disease as diagnosed by health worker
- Predictive value of health worker diagnosis
- Cost per identified true case of disease

Results

The specificity drives the cost. Even at the relatively high levels of 90 percent sensitivity and specificity, cost per identified true case of disease increases steeply to $371.04, as compared with $30.92 for perfect accuracy of diagnosis. With sensitivity and specificity equal to 50 percent, cost per identified true case of the disease increased 100-fold to $3,092.00.

Discussion

These results emphasize the need for training of health workers for accurate diagnosis. Unfortunately, current levels of sensitivity and specificity of diagnosis of leprosy are unknown. This knowledge is important for estimating costs more precisely.

Appendix 12G. General Comments about Cost-Effectiveness Modeling

It is important to note that cost per YHLG calculated by the model does not include the cost of education of the community about leprosy or of training health workers. As discussed earlier, education of the community is essential to the success of a control program. The costs of educating people about the disease are very difficult to estimate, however, and because they would probably be incorporated into other health education efforts, they would fall under the budget of multisectoral

Table 12F-1. Effect of Sensitivity and Specificity of Diagnosis on Cost per Case of Treated Leprosy

	Data entered by analyst			*Data derived by computer*		
True prevalence among persons visiting health worker (per 1,000)	*Sensitivity of health worker's diagnosis*	*Specificity of health worker's diagnosis*	*Cost per case diagnosed by health worker (dollars)*	*Prevalence of disease diagnosed by health worker (per 1,000)*	*Predictive value of health worker's diagnosis*	*Cost per identified true case of disease (dollars)*
10.00	0.99	0.99	30.92	9.91	0.500	61.84
10.00	0.90	0.90	30.92	99.01	0.083	371.04
10.00	0.90	0.80	30.92	198.01	0.043	711.16
10.00	0.90	0.70	30.92	297.01	0.029	1,051.28
10.00	0.90	0.60	30.92	396.01	0.022	1,391.40
10.00	0.90	0.50	30.92	495.01	0.018	1,731.52
10.00	0.80	0.90	30.92	99.01	0.075	413.56
10.00	0.80	0.80	30.92	198.01	0.039	796.19
10.00	0.80	0.70	30.92	297.01	0.026	1,178.83
10.00	0.80	0.60	30.92	396.01	0.020	1,561.46
10.00	0.80	0.50	30.92	495.01	0.016	1,944.10
10.00	0.70	0.90	30.92	99.01	0.066	468.22
10.00	0.70	0.80	30.92	198.01	0.034	905.51
10.00	0.70	0.70	30.92	297.01	0.023	1,342.81
10.00	0.70	0.60	30.92	396.01	0.017	1,780.11
10.00	0.70	0.50	30.92	495.01	0.014	2,217.41
10.00	0.60	0.90	30.92	99.01	0.057	541.10
10.00	0.60	0.80	30.92	198.01	0.029	1,051.28
10.00	0.60	0.70	30.92	297.01	0.020	1,561.46
10.00	0.60	0.60	30.92	396.01	0.015	2,071.64
10.00	0.60	0.50	30.92	495.01	0.012	2,581.02
10.00	0.50	0.90	30.92	99.01	0.048	643.14
10.00	0.50	0.80	30.92	198.01	0.025	1,255.35
10.00	0.50	0.70	30.92	297.01	0.017	1,867.57
10.00	0.50	0.60	30.92	396.01	0.012	2,479.78
10.00	0.50	0.50	30.92	495.01	0.010	3,092.00

Source: Authors.

health education programs rather than under that of a leprosy control program. As illustrated in appendix 12F, money spent training health care workers is money saved through reducing the number of false-positive cases diagnosed. We did not attempt to estimate the cost of this training.

It is also quite important to recognize that in the cost analysis presented in this chapter we have not considered the value of intangible benefits of a leprosy control program. Failure to consider such intangible benefits as prevention of psychological trauma when weighing the cost-effectiveness of a control program leads to serious underestimation of the benefits of such a program. This point was emphasized by Creese and Henderson (1980 p. 494): "Health programs characteristically have effects which, though important, are extremely difficult to measure and to value. Benefits such as reduced anxiety, pain, or discomfort are typical examples: these are desirable 'outputs' of the health system, but they are not readily comparable with other outputs such as increased productivity."

Appendix 12H. Total Cost of a Leprosy Control Program

In the previous appendixes, the cost-effectiveness of various aspects of a leprosy control program was discussed. In those analyses, we were considering a one-year program to treat new cases (assuming existing cases were already under treatment). We did not include capital costs and the cost of case detection, primarily because the model we used was not designed to include such costs and redesigning the model would have been a complicated undertaking beyond the scope of this project. In the following analysis, we will discuss the capital costs and the cost of case detection in the context of a five-year leprosy control program. We will then add these costs to those calculated previously for chemotherapy and complications to give an estimated total cost for a leprosy control program.

Capital Costs

The calculation of annualized capital cost will be based on a hypothetical population of 100,000 in a hyperendemic area with leprosy prevalence of 10 per 1,000 population. The capital cost will include cost of vehicles, buildings, office equipment, and laboratory equipment. The total capital cost (C) was estimated to be $100,000. The lifetime of equipment and vehicles was estimated at 10 years. The social rate of discount (r) was taken as 3 percent. The annualized discounting factor was calculated as follows:

$$\begin{aligned} a(r,n) &= \frac{[r\,(1+r)^n]}{[(1+r)^n - 1]} \\ &= \frac{.03\,(1+.03)^{10}}{(1+.03)^{10} - 1} \\ &= 0.1172. \end{aligned}$$

The annualized cost, $a(r,n)$ C, is then:

$$\begin{aligned} a(r,n)\,C &= 0.1172\ (\$100{,}000) \\ &= \$11{,}720.00. \end{aligned}$$

In a population of 100,000 in which the prevalence of leprosy is 10 per 1,000, one thousand patients would be under treatment. So the annualized capital cost per patient is:

$$\frac{\$11{,}720}{1{,}000} = \$11.72 \text{ per case.}$$

Cost of Case Detection

The cost of screening for case detection will be based on the same hypothetical population of 100,000 assumed above. Furthermore, it will be assumed that no screening has been done in the population in the previous five years. The screening team would consist of five workers, and sixty days per year for five years would be devoted to screening. It is estimated that such a team could screen 200 persons per day. Typical salaries for each such workers in a developing country would be $5 per day, with an allowance of $2 per day for travel (based on costs in Myanmar). New cases would be detected by the screening program workers at the rate of 3 cases per 1,000 screened. If the community was fairly isolated, after five years of the screening program, fewer cases would be detected because the screening and early treatment would lower incidence (the incubation period is five to seven years). We estimate that approximately half the cases would be discovered when they presented for treatment on their own initiative, rather than through the screening effort.

The total cost of the screening program per year would be as follows:

$$\text{Total cost} = (\text{salaries} + \text{travel allowance}) \times \text{no. workers} =$$
$$[(60 \cdot \$5.00) + (60 \cdot \$2.00)] \cdot 5 = \$2{,}100.00.$$

The total number of persons screened would be equal to 60 days x 200/day, or 12,000 persons. The estimated number of new cases detected would be equal to the screened population multiplied by the number of cases detected through screening, which we estimate to be 3 per 1,000, so 36 cases (12,000 · 3 per 1,000) would be detected by screening. Therefore, the screening cost per new case detected would be $2,100.00 per 36 new cases detected, or $58.34 per new case detected. An additional 36 cases would present on their own initiative for treatment. Before the screening program was started, there were 1,000 registered cases in the total population of 100,000 (prevalence, 10 per 1,000). Together, then, there are 1,000 registered cases plus 36 cases detected by screening plus 36 cases detected when they presented on their own initiative, or a total of 1,072 cases in the population of 100,000. The total cost of screening per case is, then, $2,100.00 per 1,072, or $1.96 per case.

Total Cost per Case of a Leprosy Control Program

To calculate the total cost per case of a leprosy control program, the costs of basic chemotherapy as well as treatment of complications must be added to the capital and screening costs.

COST OF BASIC CHEMOTHERAPY. As discussed in appendix 12C, the cost of treatment of uncomplicated leprosy is estimated at $30.92 per case, if it is assumed that 80 percent of cases are paucibacillary and 20 percent are multibacillary.

COST OF TREATMENT OF COMPLICATIONS. As discussed in appendix D, the cost of treatment of complications for each of those who need such treatment is estimated at $225.00. Only 10 percent of all patients are expected to need treatment for complications. Therefore, the cost of treating complications averaged over all cases, calculated by dividing the total cost for treating complications (1,000 · 0.1 · $225.00) by the total number of registered cases (1,000), is $22.50 per case.

TOTAL COST PER CASE. The sum of the estimated costs of capital, screening, chemotherapy, and treatment of complications is used to estimate the total cost per case in the leprosy control program.

Annualized capital cost	$11.72 per case
Screening	1.96 per case
Chemotherapy	30.92 per case
Complications	22.50 per case
Total	$67.10 per case

Discussion

If the screening and treatment are successful, in five to seven years (roughly the length of the incubation period of leprosy), the number of cases detected will begin to decline as the rate of transmission is reduced. As this happens, the cost per case detected will increase.

Notes

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